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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
|--------------------------|------------------|----------------------|-------------------------|-------------------------|--|
| 09/851;138 | 05/09/2001 | Geert Maertens | 2752-43 | 4881 | |
| 23117 | 7590 03/11/2003 | • | | | |
| | ANDERHYE, PC | | EXAMINER | | |
| 1100 N GLEE 8TH FLOOR | | | LI, BA | LI, BAO Q | |
| ARLINGTON | I, VA 22201-4714 | | ART UNIT | PAPER NUMBER | |
| | | | 1648 | - | |
| | | | DATE MAILED: 03/11/2003 | DATE MAILED: 03/11/2003 | |

Please find below and/or attached an Office communication concerning this application or proceeding.

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|--|---|--|-------|--|--|
| | Application No. | Applicant(s) | | | |
| | 09/851,138 | MAERTENS ET AL. | | | |
| Office Action Summary | Examiner | Art Unit | | | |
| | Bao Qun Li | 1648 | | | |
| The MAILING DATE of this communication appears on the cov r sheet with the correspondence address Period for Reply | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply If NO period for reply is specified above, the maximum statutory period we Failure to reply within the set or extended period for reply will, by statute, - Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). Status | 86(a). In no event, however within the statutory mining ill apply and will expire S cause the application to | ver, may a reply be timely filed mum of thirty (30) days will be considered timely. IX (6) MONTHS from the mailing date of this communicat become ABANDONED (35 U.S.C. § 133). | tion. | | |
| 1) Responsive to communication(s) filed on 20 D | <u>ecember 2002</u> . | | | | |
| 2a) This action is FINAL . 2b) ⊠ This | s action is non-fin | al. | | | |
| 3) Since this application is in condition for allowa closed in accordance with the practice under E Disposition of Claims | | | s is | | |
| 4) Claim(s) 63-70 is/are pending in the application | n. | | | | |
| 4a) Of the above claim(s) 64-67 and 70 is/are w | ithdrawn from co | nsideration. | | | |
| 5) Claim(s) is/are allowed. | | | | | |
| 6)⊠ Claim(s) <u>63,68 and 69</u> is/are rejected. | | | | | |
| 7) Claim(s) is/are objected to. | | | | | |
| 8) Claim(s) are subject to restriction and/or election requirement. | | | | | |
| Application Papers | | | | | |
| 9)☐ The specification is objected to by the Examiner. | | | | | |
| 10) The drawing(s) filed on is/are: a) □ accepted or b) □ objected to by the Examiner. | | | | | |
| Applicant may not request that any objection to the | | | | | |
| 11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner. | | | | | |
| If approved, corrected drawings are required in reply to this Office action. | | | | | |
| 12) The oath or declaration is objected to by the Exa | aminer. | | | | |
| Priority under 35 U.S.C. §§ 119 and 120 | | | | | |
| 13) Acknowledgment is made of a claim for foreign | priority under 35 | U.S.C. § 119(a)-(d) or (f). | | | |
| a) All b) Some * c) None of: | | | | | |
| 1. Certified copies of the priority documents have been received. | | | | | |
| 2. Certified copies of the priority documents have been received in Application No. <u>08/836,075</u> . | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | |
| 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application). | | | | | |
| a) ☐ The translation of the foreign language products) Acknowledgment is made of a claim for domestic | • • | | | | |
| Attachment(s) | - | | | | |
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7 | 5) 🔲 | Interview Summary (PTO-413) Paper No(s) Notice of Informal Patent Application (PTO-152) Other: . | _ · | | |

Art Unit: 1648

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DETAILED ACTION

Preliminary Amendment filed on 05/09/01 has been acknowledged. Claims 1-62 are canceled. New claims 63-70 are added. Amendment filed on 02/04/2002 has been noticed and the amendment of specification is entered. Claims 63-70 are pending.

Election/Restrictions

- 1. Applicant's election with traverse of Group I, claims 63, 67, 69 in Paper No. 10 is acknowledged. The traversal is on the ground(s) that claim 68 should be grouped with elected group, which is inadvertently omitted in the previous Office Action. Applicants 'argument has been considered, claim 68 is rejoined with elected group I.
- 2. Regarding to the claim 67, in consistent with the Patent Office's previous treatment of this subject matter as requested by Applicants, claim 67 is restricted from the elected group.
- 3. Applicants further require to rejoin Group III with group I since claim 65 has been amended to recited a new set of sequences, which is polypeptides encoded by the polynucleotide sequence or the modified polynucleotide sequence of group I. This request has been respectfully considered; however, it is not found persuasive because nucleic acid molecule is structurally and functionally different from the amino acid molecule, they require different search and exhibit different patentable weights.
- 4. In response to Applicants' further argue that different groups of inventions are categorized into same classification, the search of all groups of inventions in same classification would not create undue burden on the examiner. Applicants' argument has bee fully considered; however, it is not found persuasive because the criterion of Election/Restriction is not only depend on classification, they also dependent many aspects of inventions, such as different searches and patentable weights. Furthermore, because the search of different groups of inventions has to be conducted both inside house and in the commercial databases, the source of searching more than one patentable distinct subject matters are limited and constitute a serious burden for the Office.
- 5. Therefore, claims 63, 68 and 69 are considered before the examiner.

Art Unit: 1648

Applicants are reminded to amend the claims 68 and 69 to the correct dependency of claim 63 for reflecting the examination on the merits.

Priority

- 6. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:
- 7. This application filed under former 37 CFR 1.60 lacks the necessary reference to the prior application. A statement reading, "This is a division of Application No. 08/836/075, filed 04/21/1997" should be entered following the title of the invention or as the first sentence of the specification. Also, the current status of all nonprovisional parent applications referenced should be included. *Oath/Declaration*
- 8. The oath or declaration is defective because:
- 9. The full name of the first inventor (family name and at least one given name together with any initial) is not readable due to the unclearness of the copy.

Claim Rejections - 35 USC § 101

10. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

11. The invention of claim 69 is directed to non-statutory subject matter. There is no recitation of isolation or synthesis in front of the claimed polynucleic acid molecule. Therefore, the claimed polynucleic acid molecule read on naturally occurring materials, which are considered to be non-statutory and non-patenable subject matter within the scope of 35 U.S.C. 101. See Official Gazett, 1077 O.G. April 21, 1987. It is recommended that the claim incorporate the claim language, "isolated or synthesized" to overcome this rejection.

Claim Rejections - 35 USC § 112

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1648

13. Claims 63, 68 and 69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- 14. Claim 63 is vague for using a relative word of "having" in claim (i), which fails to define what is included or excluded in the structure of the claimed nucleic acid sequence. Otherwise, the claimed polynucleic acid can be interpreted as whole HCV genome having a SEQ ID NO: 51 in its genome. If Applicants wish to claim a particular nucleic acid sequence, please amend the claim by using more defined language such as " of " or "corresponding to" instead of "having". This affects the dependent claims 68 and 69.
- 15. Claim 63 is also unclear in that the metes and bounds of "a part of said polynucleic acid" are not defined. It is confusion for which part of the polynucleotide is intended in the claim. The full length of SEQ ID NO: 51 is 447 nucleic acids, and there are many arrear is unique to the HCV type 10 or subtype 10a. Depended on where the first nucleic acid starts and where the last nucleic acid ends, the unique part varies from one nucleic acid to hundreds nucleic acids. Is three nucleic acids are intended? Or more than hundred of nucleic acids intended? If Applicants wish to claim a particular fragment of a polynucleic acid fragment of SEQ ID NO: 51, please amend claim to a specific fragment with a defined SEQ ID NO: or with a defined nuclei acid position in the SEQ ID NO: 51. This affects the dependent claims 68 and 69.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 703-305-1695. The examiner can normally be reached on 8:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Art Unit: 1648

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Bao Qun Li

March 3, 2003

JAMES HOUSEL 3100
PERVISORY PATENT EXAMINER
**ECHNOLOGY CENTER 1600